In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-73V

Filed: February 12, 2019

Unpublished

DEBORAH KENT,	*	
	*	
Petitioner,	*	Ruling on Entitlement; Causation-In-Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Administration (SIRVA); Vaccine Findings of Fact; Onset of Petitioner's Shoulder Pain; Special Processing Unit (SPU)
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner.
Christine Mary Becer, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT[1]

Dorsey, Chief Special Master:

On January 17, 2017, Deborah Kent ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.,[2] (the "Vaccine Act" or "Program") for injuries, including left shoulder adhesive capsulitis and a supraspinatus tendon tear, caused in fact by the influenza vaccination she received on October 2, 2015. Petition at 1, ¶¶ 2, 14 (ECF No. 1). The case was assigned to the Special Processing Unit ("SPU").

[1] The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

During a fact hearing held on June 26, 2018 in Grand Rapids, Michigan, the undersigned made factual findings regarding petitioner's prior condition, the onset of her pain, scope of her pain and limited range of motion, and lack of other condition or abnormality. Additionally, she discussed the requirements for causation, finding that there is preponderant evidence of causation in this case. Accordingly, the undersigned finds that petitioner is entitled to compensation.

I. Procedural History

Along with the petition, petitioner filed many of the medical records required by the Vaccine Act. *See* Exhibits 1-6; *see also* § 11(c)(2) (for a description of the required medical records). A few weeks later, petitioner filed additional medical records and a statement indicating all records had been filed. *See* Exhibit 7, filed Jan. 30, 2017 (ECF No. 6); Statement of Completion, filed Jan. 30, 2017 (ECF No. 7). An initial status conference was scheduled for March 7, 2017.

During the call, the staff attorney managing this SPU case mentioned several issues which required further clarification: 1) a three-month delay in treatment of petitioner's shoulder injuries; 2) the lack of any discussion regarding petitioner's shoulder injury when undergoing a hearing check and being treated for a rash during this three-month period; and 3) the fact that petitioner had overlapping medical records from different providers. *See* Order, issued Mar. 10, 2017, at 1 (ECF No. 9). She suggested that a detailed affidavit from petitioner providing additional information regarding these issues would be helpful. *Id.* at 1-2. Additionally, the staff attorney noted that some of the medical records filed were copies contained in the medical records from other providers. She indicated petitioner should obtain all medical records directly from the providers seen by petitioner. *Id.* at 1.

On April 20, 2017, petitioner's current counsel, Amy Senerth, entered her appearance in this case.[3] (ECF No. 10). During May and June 2017, petitioner filed her additional medical records and detailed affidavit. *See* Exhibits 8-13 (ECF Nos. 11, 13). On July 7, 2017, respondent filed a status report indicating "respondent [wa]s interested in pursuing a litigative risk settlement in this case." (ECF No. 14).

Over the subsequent four months, the parties engaged in settlement discussions. *See* Status Reports, filed Aug. 21 and Oct. 6, 2017 (ECF Nos. 16, 19). On November 9, 2017, petitioner filed a status report indicating the parties had reached an impasse in their settlement discussions and that respondent wished to file a Rule 4 report by December 27, 2017.

In his Rule 4 report, respondent argued that compensation was not appropriate in this case. Respondent's Rule 4 Report ("Rule 4 Report") filed Dec. 27, 2017, at 6 (ECF No. 23). While noting that petitioner did not allege a Table Injury and observing that petitioner's case was filed prior to the addition of shoulder injury related to vaccine

[3] For the first four months of this case, petitioner was represented by C. Clark Hodgson, III, another attorney at the law firm of Muller Brazil, LLP.

administration ("SIRVA") to the Vaccine Table,[4] respondent maintained that the Table's Qualification and Aids to Interpretation ("QAI") for SIRVA are instructive in this case. The QAI for SIRVAs states:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017). Respondent asserted that the onset of petitioner's pain "was not clearly within forty-eight hours." Rule 4 Report at 6. While acknowledging "the physicians who evaluated petitioner for her shoulder pain noted the temporal association between flu shot and the shoulder pain," respondent stressed that petitioner's "orthopedist specifically noted that the flu shot did not cause the pain." *Id.* Respondent claimed petitioner failed to establish that she suffered a SIRVA within 48 hours of vaccination and thus, "has failed to meet her evidentiary burden." *Id.* The

[4] Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Table. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294 (Jan. 19, 2017); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321 (Feb. 22, 2017) (delaying the effective date of the final rule until March 21, 2017).

June 26, 2018 fact hearing was scheduled to address whether the onset of petitioner's pain occurred within 48 hours of vaccination.

Following the hearing, petitioner filed updated medical records (*see* Exhibit 16, filed Sept. 17, 2018 (ECF No. 31)) and two articles, one of which was discussed by the undersigned during the hearing, and petitioner's Medicaid lien information (*see* Exhibits 17-19,[5] filed Oct. 4, 2018 (ECF No. 32)). On January 29, 2019, the OSM staff attorney managing this SPU case contacted the parties to ask if they wished to supplement the record before the undersigned ruled on entitlement. *See* Informal Remark, dated Feb. 12, 2019. Both replied in the negative.

The matter of entitlement is now ripe for adjudication.

II. Factual History

During most of 2014, petitioner received her primary medical care from the Hart Family Medicine Center ("the Hart Center"), part of the Mercy Health Physician Partners. *See* Exhibit 2 at 53-88. From late 2014 through mid-July 2015, petitioner was seen on several occasions at Pentwater Family Medicine (*see* exhibit 4 at 7-56, 64-71). The medical records from these providers indicate that prior to vaccination, petitioner suffered occasional vertigo, routine illnesses, and common conditions. There is no mention of any shoulder issues in these records.

On October 2, 2015, petitioner transferred back to the Hart Center (referred to hereinafter as petitioner's primary care provider ("PCP")). *See* Exhibit 2 at 92. At this visit for a comprehensive physical, she received the vaccination alleged as causal. *See id.* at 90-95. The vaccination was administered intramuscularly in petitioner's left upper arm. *See* Exhibit 1; Exhibit 2 at 95.

A few days after vaccination, on October 5, 2015, petitioner followed up by telephone regarding the insurance coverage for the calcium supplement she was taking. *See* Exhibit 2 at 94 (indicating follow-up would occur), 96 (telephone call from petitioner indicating the supplement would be covered). On October 6, 2015, she visited the lab to have blood drawn for testing. *See id.* at 97-98. Petitioner faxed her completed Health Risk Assessment on October 12, 2015. *See id.* at 99-103.

On December 1, 2015, petitioner called her PCP regarding a referral to get her hearing checked. *See* Exhibit 2 at 104. She was seen on December 7, 2015, and referred to ear, nose, and throat. *See id.* at 105-07. There is no mention of shoulder

[5] These articles are S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Exhibit 17 (the one discussed by the undersigned) and M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Exhibit 18. Petitioner's Medicaid lien information was filed as Exhibit 19.

pain at this visit, and under the musculoskeletal portion of the physical examination section, it is noted only that petitioner's gait was normal.[6] *See id.* at 106.

On January 4, 2016, petitioner was seen by her PCP, complaining of left upper arm pain which began when she received the influenza vaccination. *See* Exhibit 12 at 1. She questioned whether the nurse had hit a bone during administration or the needle could be stuck in her arm. She described the pain as achy, like a toothache, and denied any neck pain, numbness, or tingling. *See id.* Upon examination, Jennifer Tate, PA,[7] observed limited range of motion ("ROM") and tenderness below the deltoid, but no shoulder swelling or tenderness. *See* Exhibit 12 at 2. Petitioner was sent for x-rays, performed the next day, which showed no fracture or other abnormality. *See id.* at 2-3.

On January 11, 2016, petitioner called her PCP for the results of her x-rays. *See* Exhibit 2 at 110. After being informed they were normal, petitioner was referred to orthopedics and an MRI was ordered.[8] *See id.* at 110-11. Conducted on January 14, 2016, the MRI showed "[p]rominent tendinosis in her supraspinatus and infraspinatus tendons" and "a small full-thickness tear in the lateral supraspinatus tendon." Exhibit 3 at 1. In light of these findings, petitioner's PCP worked diligently from January 18 through 25, to obtain an orthopedic appointment earlier than the one initially scheduled for August 2016.[9] *See* Exhibit 2 at 111-12. On January 25, 2016, an appointment was procured with a different orthopedist for the end of February 2016. *Id.*

During this time, on January 20, 2016, petitioner visited her PCP for a rash which began approximately two months earlier. *See id.* at 113. Petitioner attributed the rash to nerves, and a topical cream was prescribed. *See id.* at 114. During this visit, it was noted that petitioner was in no acute distress. *Id.* at 113. Under the musculoskeletal portion of the physical examination, it was reported only that petitioner's gait was normal. *Id.* at 114.

[6] This notation is found throughout the medical records from petitioner's PCP, usually accompanied by an additional notation that petitioner's digits/nails did not show "clubbing, cyanosis, inflammation, or ischemia." *See, e.g.,* Exhibit 2 at 70, 94. In this case, only the notation regarding petitioner's gait was included. *See id.* at 106.

[7] When petitioner visited her PCP, she was usually treated by Ms. Tate, who is a physician's assistant. *See, e.g.,* Exhibit 2 at 92 (listing Jennifer Tate as petitioner's provider).

[8] These two options were initially presented to petitioner as alternatives, with petitioner choosing a referral to orthopedics. *See* Exhibit 2 at 110. When petitioner was unable to get an appointment until August 2016, an MRI was ordered. *Id.* at 111.

[9] Because Petitioner was a Medicaid recipient, her PCP encountered difficulty getting her an orthopedic appointment in Kent county.

Petitioner was seen by Randolph Grierson, DO,[10] for left shoulder pain on February 29, 2016. *See* Exhibit 11 at 2-11; *see also* Exhibit 2 at 18-21 (copy of record sent from Dr. Grierson to Jennifer Tate, PA). At this visit, petitioner reported that her left shoulder pain began in October after receiving an influenza vaccination. She further reported that the injection was painful and that she had no left shoulder pain or weakness prior to the injection. Describing her pain as aching, she rated its severity as an eight out of ten. *See id.* at 8. Examining petitioner, Dr. Grierson observed "profoundly limited active and passive motion of the left shoulder with pain." *Id.* at 10. After reviewing petitioner's MRI, Dr. Grierson expressed his belief that "the painful injection did not cause the rotator cuff tear [which] was present before the injection," but described this finding as "incidental." *Id.* at 11. Regarding the cause of petitioner's pain,[11] Dr. Grierson concluded it "comes from an adhesive capsulitis" and indicated that her pain should subside with formal physical therapy ("PT"). *Id.* He added that other treatments, such as injections, manipulation under anesthesia, and surgery, could be considered if PT was unsuccessful. *Id.*

On March 8, 2016, petitioner began formal PT at Lakeside Comprehensive Rehabilitation ("Lakeshore Rehab"). *See* Exhibit 8 at 1-4 (initial evaluation). Petitioner's pain was depicted as occurring five months earlier (*id.* at 3), with onset listed as October 2015 (*id.* at 1). During examination, "[s]evere pain [was] noted with all shoulder ROM." *Id.* at 2. Petitioner's left deltoid pain was described as "consistent with supraspinatus pain referral pattern." *Id.* Petitioner reported difficulty when lifting, sleeping, and performing overhead and recreational activities. *Id.* at 3. Petitioner was assessed as "motivated with good potential to reach goals," but it was noted that she would be moving to another area of Michigan in three weeks. *Id.*

Petitioner attended seven PT sessions at Lakeshore Rehab from March 9 through 28. *See* Exhibit 8 at 5-18 (in reverse order). During this time, her pain improved from a level of three out of ten prior to PT and ten out of ten after PT to a prior level of one out of ten and post-level of six out of ten. *Compare id.* at 15 *with id.* at 5. She reported that her stretching was becoming easier (*id.* at 11) and that she was able to dress with greater ease (*id.* at 7). At her last session, on March 28, 2016, it was reported that petitioner's PT would be suspended while she was out of town. *Id.* at 5.

During February and March 2016, petitioner was seen at her PCP on three occasions, complaining of dry eyes, a rash, vaginitis, cough, and sore throat. *See* Exhibit 2 at 22-33. In the records from these visits under the reviewed problems section, it is noted that petitioner suffered from a "[d]isorder of bone and cartilage" with onset listed as October 2, 2015. *Id.* at 22, 25, 28. Presumably, this entry is referencing petitioner left shoulder condition. There is no further mention of petitioner's left shoulder

[10] Dr. Grierson is an orthopedic surgeon in Ludington, Michigan. *See* https://www.healthgrades.com/physician/dr-randolph-grierson-2frqm (last visited on Dec. 27, 2018). In a later record, he is described as an orthopedic surgeon. *See* Exhibit 10 at 5.

[11] The distinction between petitioner's rotator cuff tear and left shoulder pain is discussed in more detail later in this ruling. *See infra* Section V.B.

pain, and the section titled review of systems (ROS) does not include a subsection for the musculoskeletal system. *Id.* at 23-24, 27, 30-31.

After petitioner moved closer to Grand Rapids, she resumed PT at a new facility, Northern Physical Therapy Services ("Northern PT"). *See* Exhibit 6. Her initial evaluation indicated she was referred by Jennifer Tate, PA. Exhibit 6 at 53. At this first visit, petitioner described her left shoulder pain as a "sharp pain, after flu shot, [which] never went away," rating its severity as between four and seven. *Id.* She shared the results of her x-rays and MRI and indicated "Dr. Greer[12] called it frozen shoulder d/t disuse." *Id.* The evaluation lists petitioner's date of injury as November 30, 2015, but the origin of that date is not clear. Under past medical history, the record includes a notation that "[t]he patient relates this condition began on: 11-01-15." *Id.* The physical therapist who evaluated petitioner, Erin Willett, DPT,[13] assessed petitioner's tolerance during evaluation and rehabilitation potential as good. *Id.* at 57. She recommended twice weekly sessions for six weeks. *Id.*

From April 14 through June 9, 2016, petitioner attended 16 PT sessions at Northern PT. At her last session on June 9, 2016, she rated her level of pain as three out of ten and described her pain as intermittent, occurring primarily when she reached behind her back or out to the side. Exhibit 6 at 3. At her June 7, 2016 session, petitioner reported she would be seeing an orthopedist specialist, Dr. Howard, the following week. *Id.* at 8. Petitioner was discharged from PT on July 19, 2016. *Id.* at 1. Noting that petitioner's last visit was on June 9, 2016, the record indicates staff spoke to petitioner "who stated she no longer needs PT." *Id.* The record further indicates petitioner met approximately one-third of her goals (four out of twelve). *Id.* at 1-2.

On May 12, 2016, petitioner visited Grand Valley Health Plan for a health assessment. *See* Exhibit 7 at 16-20. In this record, it is noted that petitioner experienced a left rotator cuff tear in October 2015, for which she is undergoing PT. *Id.* at 16. It appears that petitioner had switched to this clinic for her primary care, as she was also seen in June 2016 for a headache (*see id.* at 12-15), in July 2016 for a spider bite (*see id.* at 7-11), and in September 2016 for a skin lesion (*see id.* at 4-6).

On June 14, 2016, petitioner was seen at a new PT facility, Spectrum Health Rehab. *See* Exhibit 9 at 11-12, 16-17 (questionnaire completed by petitioner); 25-27 (record from visit). The record from this visit indicates that petitioner reported that her left shoulder pain began in November 2015, after she received the influenza vaccination. *Id.* at 25. It was noted that petitioner's pain, rated at a level of three to seven on a scale of ten, limited her activities such as sleeping, lifting, grooming, dressing, and performing yardwork. *Id.* She was observed to have "reduced shoulder ROM, strength and posture deficits as might be expected with adhesive capsulitis." *Id.* at 26. Petitioner reported that she previously had attended PT and had made good progress. *Id.* at 25-26. Petitioner expressed her desire to be able to lift her grandson

[12] Presumably, Dr. Greer is meant to be Dr. Grierson.

[13] DPT stands for Doctorate of Physical Therapy.

and use her arm normally. *Id.* at 26. It was noted that she should benefit from additional PT, and twice weekly sessions for four to six weeks was recommended. *Id.* at 26-27.

It appears petitioner's first visit to Dr. Howard, the orthopedist mentioned during an earlier PT session, occurred on June 22, 2016. *See* Exhibit 10 at 2-29. At that visit, petitioner reported that her shoulder pain occurred suddenly and was related to her influenza vaccination. *Id.* at 5. She described her pain as located in the lateral upper arm, mild and stabbing, and "aggravated by flexing or extending the shoulder, lifting, lying on the affected side, and overhead activity." *Id.* Petitioner reported that she had undergone an MRI, been evaluated by an orthopedic surgeon and her PCP, and participated in 26 sessions of PT. *Id.* at 5-6. An evaluation of petitioner's shoulder revealed tenderness, limited ROM, and normal strength. *Id.* at 7. Petitioner shared her belief that "her shoulder [wa]s gradually improving over the last six months because of the consistent physical therapy she had been receiving" and expressed her lack of interest in a cortisone injection or surgery. *Id.* at 8. Dr. Howard cautioned that it often takes a long time to recover from adhesive capsulitis. He ordered additional PT. *Id.*

Between June 14 and August 4, 2016, petitioner attended 8 PT sessions at Spectrum Health Rehab. *See* Exhibit 9 at 56. On August 4, 2016, she indicated her level of pain had decreased, rating the severity between zero and seven. She added that she was able to do more, but continued to have difficulty reaching overhead, especially when lifting heavier objects, and behind her back. *Id.* Petitioner was assessed as showing improvement in her ROM, strength, and ability to perform certain activities. *Id.* at 57. It was noted that petitioner had improved her ROM by between 10 to 15 degrees (*id.* at 58), but some limitation was still observed (*id.* at 57, ranking ROM at four out of five). Petitioner had partially met her goal of being able to lift her grandson to eye level without pain. *Id.* at 58.

III. Legal Standard for Entitlement

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1). § 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. § 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[14] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case

[14] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. § 11(c)(1)(C). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a).

Because this petitioner's claim predates the inclusion of SIRVA on the Table, she must prove her claim by showing that her injury was caused-in-fact by the vaccination in question. § 11(c)(1)(C)(ii). The Federal Circuit has held that to establish causation, a petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

IV. Fact Hearing

A. Applicable Legal Standard for Factual Findings

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health &*

Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

B. Testimony

During the fact hearing held in Grand Rapids, Michigan on June 26, 2018, the undersigned heard testimony from petitioner and her husband. Petitioner testified first and described the details surrounding the vaccination alleged as causal, the subsequent treatment she received, and severity and effects of her injury. Petitioner's husband provided testimony regarding his interactions with his wife following vaccination and limitations he observed.

Petitioner testified that she received the vaccination alleged as causal when visiting the Hart Clinic for a physical on October 2, 2015. Transcript ("Tr.") at 5-7. Although she indicted she had been going to the clinic for approximately two and a half years, she testified that she had not seen the nurse who administered the vaccination previously. Tr. at 6. Petitioner recalled many of the details surrounding the vaccination, indicating that it occurred after the doctor left the room and was administered in her left arm while she was sitting with her top off and the nurse was standing. Tr. at 6-7. Petitioner stated that, due to a fear of needles, she tried not to look while the vaccination was being administered but felt immediate pain upon injection, worse than what she had felt with previous vaccinations. Tr. at 7-8. She asked the nurse if she broke the needle off in her arm. Tr. at 7. Petitioner testified that the nurse reacted harshly and, in response to petitioner's request to speak to the doctor, informed her that she had left because it was homecoming. Tr. at 8. When petitioner's counsel asked petitioner if she had suffered from any prior shoulder injuries, petitioner replied that she had not. Tr. at 9-10.

Describing the events following vaccination, petitioner indicated she returned home and cried to her husband. Tr. at 10. In response, he gave her an ice pack and told her that the nurse may have bruised her bone. In addition to the ice pack, petitioner took Tylenol and tried heat to see if that would alleviate her pain. She stated that she slept in the recliner that night. When asked to describe the injection site, petitioner testified that she did not notice any redness or swelling but did have tenderness which felt better when she pressed on it slightly. Tr. at 10. She continued to apply ice and heat the next day and accompanied her husband to the store when he cautioned that she did not want her shoulder to become stiff. Tr. at 11.

Petitioner testified that, a few days later, she returned to the laboratory, located at the back of her doctor's office, to have blood drawn. Tr. at 11. She stated that she informed the technician of her left arm pain and was told that a man who was seen before her had a similar complaint. Tr. at 12. After examining her arm, the technician assured her that some people take longer to heal after a vaccination and that she should continue to apply ice and heat and to take Tylenol. Petitioner testified that she complained of her pain again when she called the clinic a few days later to obtain her cholesterol results. Tr. at 12. After being reassured that some people take longer to heal and being asked if she was experiencing a fever, petitioner declined to make an appointment. Tr. at 12-13. Petitioner could not recall to whom she spoke but guessed that it may have been Dana, a nurse with whom she was familiar. Tr. at 13.

Petitioner then described the difficulties she experienced sleeping and performing common tasks such as shampooing her hair. Tr. at 13. She indicated that eventually, her arm became frozen to her side, as if hanging in a sling. Tr. at 14. She stated that her husband had to do everything for her. Tr. at 15.

Regarding treatment, petitioner testified that she was seen by her PCP in January 2016 and underwent x-rays and an MRI. Tr. at 17. Although she could not recall the name of the orthopedist she saw in February 2016, she remembered that he prescribed medication, including muscle relaxers which made her sick, gave her exercises to perform, and arranged formal PT. Tr. at 18. She described the PT, began on March 8, 2016. Tr. at 21-23.

Petitioner testified further regarding the activities she was unable to do, such as lifting her iron skillet, knitting, or holding her grandson, and ways she had adapted such as using a stool when getting items from the cabinet. Tr. at 25-28.

When asked why she declined a cortisone shot, petitioner expressed her dislike for doctors, needles, and surgery. Tr. at 29. Regarding the notation in the medical records from Northern PT, indicating petitioner's pain began on November 30, 2015, petitioner surmised that it may be a typo or that she may have provided that date. Tr. at 29. However, she could think of no reason why she would have indicated November 30, 2015, adding that she believed she was at her daughter's house for Thanksgiving on that day. Tr. at 29-30.

During cross examination, respondent's counsel asked petitioner if she had called the doctor's office regarding her left shoulder pain at any time besides the call to Dana which had already been discussed. Petitioner thought she had called an additional time before traveling to her daughter's house for Thanksgiving but could not understand why that call was not noted in the medical records. Tr. at 33-34. When respondent's counsel asked about specific activities: lifting her iron skillet, washing her hair, and putting on her bra, petitioner stated she could do all activities with an adjustment needed when lifting the iron skillet. Tr. at 40.

In response to questioning from the undersigned, petitioner pointed to the physical location where she received the influenza vaccination, "where the humerus inserts into the shoulder joint." Tr. at 41. When the undersigned asked if anyone else had indicated the vaccination was administered too high, petitioner replied that Dr. Howard had. She added that he was "the only one who believed [her, and that] . . . he had heard of this flu vaccine having resulted in injuries to the shoulder on many of his patients." Tr. at 43. According to petitioner, Dr. Howard "recommended a better physical therapy program at a fitness spa," which was why she stopped going to Northern PT. Tr. at 43. Presumably, the PT facility recommended by Dr. Howard was Spectrum Health Rehab, which petitioner visited in June through early August 2016. Petitioner confirmed that she had stopped formal PT because she had reached her goals, had not gone to an orthopedist since last seeing Dr. Howard in June 2016, and that she had not received and did not plan to receive a cortisone injection or undergo surgery. Tr. at 54.

During his testimony, petitioner's husband confirmed that petitioner had complained of her shoulder pain shortly after vaccination and that he was required to help her with many of her normal activities. Tr. at 57-63. He testified that petitioner experienced pain the evening after vaccination and was unable to sleep. Tr. at 58. He did not recall the events of the next day but verified that he recommended petitioner seek medical care. Tr. at 60. When asked about petitioner's current condition, he indicated she was doing well. He stated that he still helps petitioner put away dishes that are kept in a higher location but attributed that in part to her short stature. Tr. at 63. He testified that he knew of no shoulder injury experienced by petitioner prior to the vaccination alleged as causal. Tr. at 64.

During cross examination, respondent's counsel asked petitioner's husband for additional details regarding his time as a military medic, which he had mentioned earlier. he stated he worked as a medic from 1964 to 1966 and often gave shots as part of his duties. Tr. at 64-65. He also provided details regarding the preparation of his affidavit and confirmed he was present when his wife first complained of her left shoulder pain during a telephone call to her PCP. Tr. at 65-66.

C. Factual Findings

Respondent does not dispute that petitioner received the vaccination alleged as causal intramuscularly in her left deltoid on October 2, 2015. Rather, the primary disagreement in this case involves the timing of the onset of petitioner's left shoulder injury.

1. Onset of Pain

While acknowledging the case predates the inclusion of SIRVA as a Table injury, respondent argues that compensation is not appropriate because the onset of petitioner's pain "was not clearly within forty-eight hours," the time period required for a Table SIRVA. Rule 4 Report at 6; *see* 42 C.F.R. § 100.3(a)(XIV)(B) (noting onset for a

Table SIRVA following receipt of the influenza vaccination must occur within 48 hours). However, there are additional Vaccine Act provisions the undersigned finds instructive in this case. Under Section 13 of the Act, the special master may find the time period for the first symptom or manifestation of onset required for a Table injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset . . . occur within the time period described in the Vaccine Injury Table." *Id.*

As the undersigned stated at the fact hearing, there are multiple entries in the medical records which provide circumstantial evidence that the onset of petitioner's pain occurred within 48 hours of vaccination. Tr. at 70-71. When first treated for her left shoulder pain by her PCP on January 4, 2016, petitioner reported that her pain began when she received the influenza vaccination in early October 2015. *See* Exhibit 12 at 1. Dr. Grierson's record from his initial visit with petitioner on February 29, 2016, reflects that the onset of petitioner's pain was in October, "after the flu shot." Exhibit 11 at 8; Exhibit 2 at 18. Records from visits to petitioner's PCP for other conditions in February and March 2016, list the onset of petitioner's bone and cartilage disorder as October 2, 2015. Exhibit 2 at 22, 25, 28. The medical record from petitioner's initial PT evaluation at Lakeshore Rehab on March 8, 2016, depicts petitioner's pain as occurring five months earlier. Exhibit 8 at 3. Onset is listed as October 2015. *Id.* at 1. When petitioner visited Grand Valley Health Plan for a health assessment in May 2016, she reported that she suffered a left rotator cuff tear in October 2015, for which she was undergoing PT. Exhibit 7 at 16. When seen by Dr. Howard in June 2016, petitioner indicated that her left shoulder pain occurred suddenly and was related to her influenza vaccination. Exhibit 10 at 5.

The undersigned recognizes these entries are from medical histories provided by petitioner. As the Federal Circuit has noted, it is appropriate for a special master to give greater weight to evidence contained in medical records created closer in time to the vaccination, even if the information is provided as part of a medical history. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). The Circuit Court explained that

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id.

The only medical records containing entries which suggest petitioner's onset was later are those from PT sessions at Northern PT beginning on April 14, 2016, and at Spectrum Health Rehab beginning on June 14, 2016. The records from Northern PT

list November 30, 2015 as the date of petitioner's injury. *E.g.,* Exhibit 9 at 53. However, those records also indicate petitioner's condition began on November 1, 2015, and that her pain, described as sharp, began after her flu shot and never went away. *E.g., id.* Entries found in the records from Spectrum Health Rehab state that petitioner reported her pain began in November 2015, but also link onset to the influenza vaccination. *E.g.,* Exhibit 9 at 25. Throughout the medical records, including those which provide an onset date in November 2015, petitioner consistently indicated her pain was immediate, upon vaccination.

At the hearing, petitioner testified that her pain was sharp and immediate upon vaccination. As indicated at the hearing, the undersigned finds petitioner's testimony persuasive and credible. Tr. at 71. Even without this testimony, the evidence contained in the medical records supports petitioner's assertion that her pain was immediate.

The undersigned finds that the overwhelming preponderance of the evidence, as well as petitioner's testimony, establish that the onset of petitioner's pain was immediate and thus, within 48 hours of vaccination.

2. Prior Condition

At the hearing, the undersigned issued further findings regarding the criteria for a Table SIRVA. Regarding petitioner's prior condition, she stated that she finds the petitioner "had no history of pain, inflammation, or dysfunction of her left shoulder prior to her . . . flu vaccine administration." Tr. at 69. She based this finding on a review of systems performed by petitioner's PCP on April 2, 2014, the assessment by Dr. Grierson in late February 2016, and the testimony of petitioner and her husband. Tr. at 69. In the April 2, 2014 record, under the musculoskeletal portion of the review of systems, it is noted that petitioner had "No muscle or joint pain, weakness, swelling or inflammation. No restriction of motion, no atrophy or backache." Exhibit 2 at 69. Referring to petitioner's influenza vaccination, Dr. Grierson indicated that petitioner "did not have any pain or weakness in the left shoulder before this injection." Exhibit 11 at 8; *see also* Exhibit 2 at 18.

The undersigned finds there is no evidence that petitioner experienced any prior issues with her left upper arm/shoulder.

3. Scope of Pain and Limited ROM

Based on the testimony from petitioner and her husband and the medical records from Dr. Grierson, the undersigned indicated that she finds petitioner's symptoms were limited to her left shoulder. Tr. at 71. In the record from petitioner's February 29, 2016 visit, Dr. Grierson described petitioner's pain as located in her lateral shoulder, adding that it was not radiating. Exhibit 11 at 8; *see also* Exhibit 2 at 18. Upon examination, he observed "profoundly limited active and passive motion of [petitioner's] left shoulder with pain." Exhibit 11 at 10 (emphasis added). There is no entry indicating petitioner experienced pain or limited ROM in any area other than her left upper arm/shoulder.

The undersigned finds there is sufficient evidence to show petitioner's pain and reduced ROM to be limited to her left upper arm/shoulder.

4. Other Condition or Abnormality

At the hearing, the undersigned stated that she finds the last criteria for SIRVA was also satisfied. Dr. Grierson identified no other condition or abnormality which would explain petitioner's symptoms. Recognizing that Dr. Grierson had opined that the rotator cuff injury shown on petitioner's MRI occurred prior to vaccination, the undersigned explained that such older, asymptomatic injuries were quite common in SIRVA cases. She indicated that the S. Atanasoff article explained the phenomena and would be filed subsequent to the hearing. Tr. at 73; *see infra* Section V.B. (for further discussion of S. Atanasoff Article).

The undersigned finds there is nothing in the medical records filed or testimony given which points to another condition or abnormality which would cause petitioner's symptoms.

V. Ruling on Entitlement

In order to receive compensation under the Vaccine Act, petitioner must prove causation by satisfying the three-pronged test set forth in *Althen* by the preponderance of evidence standard required in the Vaccine Act. 418 F.3d at 1278. In *Althen,* the Federal Circuit described this standard "as one of proof by a simple preponderance, of 'more probable than not' causation." *Id.* at 1279.

Although the first and second prongs of *Althen* appear to be similar, these analyses involve different inquiries. *See Doe 93 v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 553, 566-67 (2011). The first prong focuses on general causation, whether the administered vaccine can cause the particular injury suffered by the petitioner, and the second prong focuses on specific causation, whether the administered vaccine did cause the injury. *Pafford v. Sec'y of Health & Human Servs.,* 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). This distinction "has been described as the 'can cause' vs. 'did cause' distinction." *Stapleford v. Sec'y of Health & Human Servs.*, No. 03-234V, 2009 WL 1456441, at *18 (Fed. Cl. Spec. Mstr. May 1, 2009).

A. First *Althen* Prong

As the undersigned stated at the conclusion of the fact hearing (Tr. at 73), the mechanism for a SIRVA injury is well described in medical literature. When proposing the addition of SIRVA to the Vaccine Table, respondent discussed the means by which this injury is caused. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015). Specifically mentioned as supporting this causal link are the two articles filed in this case as Exhibits

17-18. *Id.* The undersigned takes judicial notice of the fact that respondent has added SIRVA after receipt of an intramuscularly administered seasonal influenza vaccine to the Table. Such recognition of the causal link between vaccine and injury has been held to support the establishment of the theory require by the first *Althen* prong. *See Doe 21 v. Sec'y of Health & Human Servs.,* 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013).

Additionally, the undersigned notes that, prior to the adoption of the revised Table, which is effective for petitions filed on March 21, 2017 and later, respondent has conceded entitlement in numerous SIRVA cases, alleging causation by an intramuscularly administered influenza vaccine. *See, e.g.*, *Cothern v. Sec'y of Health & Human Servs.,* No. 14-574V, 2014 WL 6609687 (Fed. Cl. Spec. Mstr. Oct. 15, 2014); *MacLaughlin v. Sec'y of Health & Human Servs.,* No. 17-57V, 2018 WL 3030269 (Fed. Cl. Spec. Mstr. Mar. 16, 2018). Even after the revised Table became effective, respondent has continued to concede cases which may not meet the Table criteria, but in which respondent, nevertheless, believes causation has been established. *See, e.g., Buras v. Sec'y of Health & Human Servs.,* No. 17-1012V, 2018 WL 4042194 (Fed. Cl. Spec. Mstr. Apr. 13, 2018).

The undersigned finds the evidence discussed above comprises preponderant evidence sufficient to show that the seasonal influenza vaccine, when administered intramuscularly, can cause SIRVA. General causation is established, and petitioner has satisfied the first *Althen* prong.

B. Second and Third *Althen* Prongs

Although petitioner's claim does not constitute a Table Injury, the undersigned finds the QAI criteria for SIRVA to be informative when determining if petitioner has shown the influenza vaccination she received caused her injury in an appropriate time frame sufficient to establish a proximate temporal relationship between vaccination and injury. The four criteria listed in the QAI are as follows:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
> (ii) Pain occurs within the specified time frame;
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10)(i)-(iv). As noted in Section IV above, the undersigned finds that all four criteria are satisfied by preponderant evidence in this case.

With regard to the second *Althen* prong, the undersigned finds there is a preponderance of evidence in the exhibits filed and testimony given to support a logical sequence of cause and effect showing the October 2, 2015 influenza vaccination to be the cause of petitioner's left shoulder pain. Tr. at 73; *see Althen,* 418 F.3d at 1278. Petitioner's injury meets the criteria for a SIRVA injury and the clinical course of petitioner's injury mirrored what is seen typically in a SIRVA.

Although Dr. Grierson opined that the rotator cuff tear seen on petitioner's MRI predated the October 2, 2015 vaccination (exhibit 11 at 11), the undersigned addressed this entry during the fact hearing. As the undersigned explained, "[t]here are a number of us who are over a certain age who will have rotator cuff tears seen on MRI which are asymptomatic, but after the flu shot causing inflammation, may become symptomatic." Tr. at 73. The phenomena, where a common asymptomatic condition such as a rotator cuff tear becomes symptomatic after provoked by trauma or other events, is discussed in the S. Atanasoff article. *See* Exhibit 17 at 3. The authors explained, "some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." *Id.*

Moreover, it is important to note that the statement by Dr. Grierson addresses only the cause of the rotator cuff tear, not the cause of petitioner's shoulder pain. Regarding petitioner's left shoulder pain, it appears Dr. Grierson accepts the influenza vaccination as the cause. He refers to the injection as the mechanism of injury, describing it as painful; lists October 2, 2015 as the date of the onset of petitioner's injury; and attributes petitioner's pain not to the older rotator cuff tear but to the adhesive capsulitis currently suffered by petitioner. *See* Exhibit 11 at 8, 11; *see also* Exhibit 2 at 18, 22 (copy provided to petitioner's PCP). Significant in that regard, adhesive capsulitis is itself consistent with SIRVA. When proposing to add SIRVA to the Vaccine Injury Table, respondent specifically identified adhesive capsulitis or frozen shoulder syndrome as "diagnoses, beyond deltoid bursitis, that resulted in shoulder pain following vaccination." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136 (July 29, 2015).

There is no entry in the medical records from the second orthopedist who treated petitioner, Dr. Howard, regarding the cause of petitioner's injury. *See* Exhibit 10. However, petitioner testified that he suggested her vaccination was administered too high, at the top of her shoulder, described SIRVA injuries, and recommended a different ("better") physical therapy program. Tr. at 38. Petitioner confirmed Dr. Howard was "the first health care provider who understood or seemed to understand . . . the association between the flu shot and the problem with [petitioner's] shoulder." Tr. at 41. As stated by the undersigned at the conclusion of the fact hearing, regarding the logical sequence of cause and effect, based upon the totality of the facts and circumstances set forth in the exhibits and given in the testimony, there is preponderant evidence of

causation due to the clinical course and the clinical presentation of petitioner's right shoulder injuries. Tr. at 64.

Additionally, as stated in Section IV.C.1. above, the undersigned finds the onset of petitioner's left shoulder pain occurred within 48 hours of vaccination. The timing of onset shows a proximate temporal relationship between vaccination and injury. *See Althen,* 418 F.3d at 1278.

The undersigned finds the evidence discussed in this ruling qualifies as preponderant evidence to show the influenza vaccination administered to petitioner caused her shoulder injury within the time frame required. Specific causation is established, and petitioner has satisfied the second and third *Althen* prongs.

VI. Conclusion

Based on the record as a whole, including the testimony of petitioner and her husband, the undersigned finds by preponderant evidence that (1) petitioner had no prior problem with her left upper arm/shoulder; (2) the onset of petitioner's pain occurred within 48 hours, specifically immediately upon vaccination; (3) petitioner's pain and reduced ROM were limited to her left upper arm/shoulder; and (4) petitioner had no prior condition or abnormality that would explain her symptoms. Thus, the criteria for a Table Injury of SIRVA, effective for petitions filed on or after March 21, 2017, is satisfied in this case. There is preponderant evidence to satisfy the three-pronged *Althen* test and to establish petitioner's October 2, 2015 influenza vaccination caused her left shoulder pain and resulting adhesive capsulitis. **The undersigned finds that petitioner is entitled to compensation in this case.**

Any questions about this ruling and order or about this case generally may be directed to OSM staff attorney, Stacy Sims, at (202) 357-6349 or email: Stacy_Sims@cfc.uscourts.gov.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master